PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY
(PCT Rule 43*bis*.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/IL2008/000406	24.03.2008	01.05.2007

International Patent Classification (IPC) or both national classification and IPC
INV. A61B5/00 B25G3/38
ADD. A61B6/00 A61B8/00 A61B19/00

Applicant
DUNE MEDICAL DEVICES LTD.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notifed the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:	Date of completion of this opinion	Authorized Officer
European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	see form PCT/ISA/210	Görlach, Tobias Telephone No. +31 70 340-4214

Form PCT/ISA/237 (Cover Sheet) (April 2005)

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/IL2008/000406

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of:

   ☒ the international application in the language in which it was filed

   ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(a))

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material:

      ☐ a sequence listing

      ☐ table(s) related to the sequence listing

   b. format of material:

      ☐ on paper

      ☐ in electronic form

   c. time of filing/furnishing:

      ☐ contained in the international application as filed.

      ☐ filed together with the international application in electronic form.

      ☐ furnished subsequently to this Authority for the purposes of search.

4. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of

☐ the entire international application

☒ claims Nos. 6-8,14-52

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international search *(specify)*:

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed *(specify)*:

☒ no international search report has been established for the whole application or for said claims Nos. 6-8,14-52

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

- ☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.
- ☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.
- ☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13*ter*.1(a) or (b).

☐ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions, and such tables were not available to the International Searching Authority in a form and manner acceptable to it.

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See Supplemental Box for further details

Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees, the applicant has, within the applicable time limit:

   ☐ paid additional fees

   ☐ paid additional fees under protest and, where applicable, the protest fee

   ☐ paid additional fees under protest but the applicable protest fee was not paid

   ☒ not paid additional fees

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is

   ☐ complied with

   ☒ not complied with for the following reasons:

   see separate sheet

4. Consequently, this report has been established in respect of the following parts of the international application:

   ☐ all parts.

   ☒ the parts relating to claims Nos. 1-5,9-13

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	5,10,12,13
	No:	Claims	1-4,9,11
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-5,9-13
Industrial applicability (IA)	Yes:	Claims	1-5,9-13
	No:	Claims	

2. Citations and explanations

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item IV
Lack of unity of invention

1. The separate groups of inventions are:

I.1 Claim 5 directed to improved tissue contact;
I.2 Claims 10, 12 and 13 directed to particular types of measurement.
II. Claims 6 and 14-26 directed to improved visibility of the observed tissue in the dark;
III. Claims 7 and 27-39 directed to improved recognition of diseased tissue;
IV. Claims 8 and 40-52 directed to avoiding view obstruction by the device

They are not so linked as to form a single general inventive concept (Rule 13.1 PCT) for the following reasons:

2. Reference is made to the following document:

D1: US 6 093 150 A

3.1 Document D1 discloses all the features of claim 1 (the references in parentheses refer to this document):

An ergonomic (column 10, lines 6-8) device (100) for intraoperative tissue characterization, comprising:
a body, which comprises:
proximal (7) and distal (9) portions, with respect to the tissue, as it is characterized;
a gripping handle (9), at the distal portion; and
a sensor head (6), at the proximal portion, the sensor head comprising at least one sensor (6) for tissue characterization,
wherein the gripping handle and the sensor head are arranged at an angle a, wherein in absolute value, a > 10 degrees (Fig. 2b).

3.2 Document D1 also discloses all the additional features of the following claims dependent on claim 1:

- Claim 2: see column 8, lines 22-36 and Figs. 4a-b.
- Claim 3: see column 8, lines 35-56 and Figs. 2a-4b.
- Claim 4: see column 7, lines 4-7 and column 8, lines 35-56.
- Claim 9: see column 6, lines 28-43.
- Claim 11: see column 6, lines 38-41 and Figs. 4a-4d.

3.3 Furthermore, document D1 discloses the following features of the other independent claims 14, 27 and 40:

> An ergonomic (column 10, lines 6-8) device (100) for intraoperative tissue characterization, comprising:
> a body, which comprises:
> proximal (7) and distal (9) portions, with respect to the tissue, as it is characterized;
> a gripping handle (9), at the distal portion; and
> a sensor head (6), at the proximal portion, the sensor head comprising at least one sensor (6) for tissue characterization.

3.4 Therefore, regarding the remaining dependent claims of claim 1 and the other independent claims 14, 27 and 40, the following special technical features (STF) can be recognized (Rule 13.2 PCT):

- Claim 5: sensor head includes vacuum system;
- Claims 6 and 14: sensor head includes light fixture;
- Claims 7 and 27: sensor head includes marking module;
- Claims 8 and 40: sensor head includes transparent frame;
- Claim 10: sensor of a particular type;
- Claim 12: at least two different types of sensors;
- Claim 13: sensors of particular types.

3.5 The technical problems solved by these special technical features can be regarded as follows:

- Claim 5: Improved tissue contact;

- Claims 6 and 14: Improved visibility of tissue being observed in the dark;
- Claims 7 and 27: Improved recognition of diseased tissue;
- Claims 8 and 40: Avoiding view obstruction by the device;
- Claims 10, 12 and 13: Performing measurements of a certain type.

3.6. Hence, the following special technical features can be regarded as corresponding STF in the sense of Rule 13.2 PCT:

1) Claim 5: Vacuum system;
2) Claims 6 and 14: Lighting means for the tissue;
3) Claims 7 and 27: Marking device;
4) Claims 8 and 40: Transparent frame around the sensor head;
5) Claims 10, 12 and 13: Particular types of sensor(s).

3.7 In conclusion, the groups of claims are not linked by common or corresponding special technical features and define 5 different inventions not linked by a single general inventive concept.
The application, hence does not meet the requirements of unity of invention as defined in Rules 13.1 and 13.2 PCT.

3.8 Since the claims of group 5) have been searched, this opinion will also be established for these claims.

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. First of all, it should be noted that "for" in a device claim is to be interpreted as "suitable for" (PCT Guidelines, 5.23).

2. Reference is made to the following documents:

D1: US-A-6 093 150 (CHANDLER PAUL E [US] ET AL) 25 July 2000 (2000-07-25)

D2: US 2002/148277 A1 (UMEDA MANABU [JP]) 17 October 2002 (2002-10-17)
D3: US 2005/119648 A1 (SWANSON DAVID K [US]) 2 June 2005 (2005-06-02)

3. The present application does not meet the criteria of the PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT.

3.1 The document D1 discloses (the references in parentheses applying to this document):

An ergonomic (column 10, lines 6-8) device (100) for intraoperative tissue characterization, comprising:
a body, which comprises:
proximal (7) and distal (9) portions, with respect to the tissue, as it is characterized;
a gripping handle (9), at the distal portion; and
a sensor head (6), at the proximal portion, the sensor head comprising at least one sensor (6) for tissue characterization,
wherein the gripping handle and the sensor head are arranged at an angle a, wherein in absolute value, a > 10 degrees (Fig. 2b).

3.2 Document D2 also discloses all the features of claim 1, see paragraphs 61-68 and Figs. 1, 4 and 5.

4. Dependent claims 2-5 and 9-13 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step:

4.1 Novelty (Article 33(2) PCT):

- Claim 2: see D1, column 8, lines 22-36 and Figs. 4a-b; see also D2, paragraphs 67-70 and Fig. 4.
- Claim 3: see D1, column 8, lines 35-56 and Figs. 2a-4b.
- Claim 4: see D1, column 7, lines 4-7 and column 8, lines 35-56.
- Claim 9: see D1, column 6, lines 28-43; see also D2, paragraph 62.
- Claim 11: see D1, column 6, lines 38-41 and Figs. 4a-4d, and D2, paragraph 62.

4.2 Inventive Step (Article 33(3) PCT):

- Claim 5: see D3, paragraphs 92-99 and Fig. 7.
- Claims 10, 12 and 13: see D3, paragraphs 120 and 129.

Re Item VIII

Certain observations on the international application

1. In claims 12 and 13, the wording "the at least one sensor includes at least two different types of sensors" is not clear (Article 6 PCT). In order to include at least two different types of sensors, there have be at least two sensors, rather than at least one sensor.

Possible steps after receipt of the international search report (ISR) and written opinion of the International Searching Authority (WO-ISA)

General information	For all international applications filed on or after 01/01/2004 the competent ISA will establish an ISR. It is accompanied by the WO-ISA. Unlike the former written opinion of the IPEA (Rule 66.2 PCT), the WO-ISA is not meant to be responded to, but to be taken into consideration for further procedural steps. This document explains about the possibilities.
Amending claims under Art. 19 PCT	Within 2 months after the date of mailing of the ISR and the WO-ISA the applicant may file amended claims under Art. 19 PCT directly with the International Bureau of WIPO. The PCT reform of 2004 did not change this procedure. For further information please see Rule 46 PCT as well as form PCT/ISA/220 and the corresponding Notes to form PCT/ISA/220.
Filing a demand for international preliminary examination	In principle, the WO-ISA will be considered as the written opinion of the IPEA. This should, in many cases, make it unnecessary to file a demand for international preliminary examination. If the applicant nevertheless wishes to file a demand this must be done before expiry of 3 months after the date of mailing of the ISR/WO-ISA or 22 months after priority date, whichever expires later (Rule 54bis PCT). Amendments under Art. 34 PCT can be filed with the IPEA as before, normally at the same time as filing the demand (Rule 66.1 (b) PCT). If a demand for international preliminary examination is filed and no comments/amendments have been received the WO-ISA will be transformed by the IPEA into an IPRP (International Preliminary Report on Patentability) which would merely reflect the content of the WO-ISA. The demand can still be withdrawn (Art. 37 PCT).
Filing informal comments	After receipt of the ISR/WO-ISA the applicant may file informal comments on the WO-ISA directly with the International Bureau of WIPO. These will be communicated to the designated Offices together with the IPRP (International Preliminary Report on Patentability) at 30 months from the priority date. Please also refer to the next box.
End of the international phase	At the end of the international phase the International Bureau of WIPO will transform the WO-ISA or, if a demand was filed, the written opinion of the IPEA into the IPRP, which will then be transmitted together with possible informal comments to the designated Offices. The IPRP replaces the former IPER (international preliminary examination report).
Relevant PCT Rules and more information	Rule 43 PCT, Rule 43bis PCT, Rule 44 PCT, Rule 44bis PCT, PCT Newsletter 12/2003, OJ 11/2003, OJ 12/2003